

## REMARKS

Amended independent claim 15, upon which all other claims depend, is directed to a self-treatment process for periodontal patients with gingival detachment of about 3 mm and greater including three steps for the removal of biofilms on a daily basis from supragingival, interproximal and subgingival tooth surfaces, using three specific dental devices to deliver soft abrasives to the required tooth surfaces, combined with the working of the soft abrasives into the biofilms on these tooth surfaces to disrupt and remove the same. Biofilm is defined in the specification as filed, as follows:

Aged plaque is now described as a biofilm. Biofilms below the gumline and between teeth are recognized as the host for those pathogens responsible for gum disease, as well as C-reactive protein which is identified with heart disease. Throughout nature, biofilms have a reputation for being notoriously difficult to remove. Biofilms are unique ecosystems that are most pervasive; they extend from “slimes” common to various industrial processes to inflammation in humans and animals.

Nothing in the cited prior art teaches the claimed method, and allowance of the new claims is respectfully requested.

Claim Rejections - 35 U.S.C. § 112

Claims 15-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In view of the amendments made to Claim 15, this rejection may now be withdrawn. Such action is respectfully requested.

Claim Rejections - 35 U.S.C. § 103

Claims 15-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller, US 5,129,824 ('824) taken with Hill, US 5,993,784 (784) and Hill et al., US 5,057,309 ('309) in view of Kim et al., US, 6,045,800 ('800). This rejection is respectfully traversed.

Keller teaches a method to treat periodontal disease which entails the delivery of a medicament in close proximity to the bone and supporting structure of the teeth. Keller is not directed to a method of removing biofilm. In fact, the term "biofilm" does not appear in the Keller specification. Instead, Keller teaches a method of treating infection of gum tissue.

As taught therein, a medicament is preferably forcibly delivered directly to the infected site by flossing, brushing, or injection through the use of tufted floss, an interdental brush or syringe, respectively, or by hydrostatic or mastication pressure through the use of a tray appliance or the like. Preferably, the flossing or brushing application is carried out using a piece of floss or an interdental toothbrush which carries a supply of the medicament. The floss preferably has tufted section which enhances the carrying capability of the floss. The application of medicament by floss or interdental toothbrush may be supplemented by application of the medication in a flexible tray appliance molded of a suitable synthetic resin material or elastomeric material to conform to the patient's teeth so as to fit closely on the teeth and supporting structure. Preferably, the medicament used with the floss or brush delivery device is an antibiotic, such as a tetracycline solution. The medicament used with the tray delivery device is preferably a combination of a tetracycline solution and a hydrogen peroxide (oxygenator) gel such that as the hydrogen peroxide decomposes into oxygen and water within the gap between the patient's teeth and the form fitted tray, the antibiotic is forced by hydrostatic pressure beneath the gingiva directly to the infected site. The oxygen rich environment within the

tray appliance resulting from the decomposition of the hydrogen peroxide decreases the activity of anaerobic microorganisms in the gingiva area.

As an additional teaching, Keller states that “Antiplaque medications may also be used to decrease plaque build-up.” Specifically, Keller states that:

It will further be noted that with the tray 65, other medicaments, including fluoride, dichloride medicaments, or a suitable anti-plaque medication (e.g., an anti-plaque medication containing sodium monofluorophosphate or sanquinria) can be used so as to decrease microbial activities or plaque formation.

Hill '784 teaches a low foaming toothpaste formulation containing an abrasive, a humectant, a surfactant and a foam controlling agent wherein the abrasive/tooth surface interface and abrasive packing is delivered using a channeled bristle toothbrush. The toothpaste formulation further containing one or more active ingredients for the treatment of oral conditions ranging from chronic plaque and tartar buildup to gingivitis, caries, hypersensitivity, etc. Nothing in Hill '784 is directed to soft abrasives.

Instead, the patent teaches conventional dental abrasives, that is, abrasive materials that include talc, calcium pyrophosphate, calcium hydrogen phosphate dihydrates, anhydrous dicalcium phosphate, calcium carbonate, alumina, tin dioxide, silica, zirconium silicate, sodium bicarbonate, sodium percarbonate, etc., and mixtures thereof. Particularly preferred are abrasive mixtures where the secondary abrasive is the type used in translucent dentifrice gels at levels up to about 20%.

Hill '309 teaches ingestible, non-foaming, non-aqueous liquid and semi-solid, oral hygiene preparations containing a nonionic surfactant, a coating substance insoluble in said surfactant, and a microbially active form of stannous fluoride ( $\text{SnF}_2$ ). These oral hygiene preparations have utility in treating caries, plaque fighting and in gingivitis

control as well as for the treatment of hypersensitive teeth, various *Candida sp.* conditions, and other disorders of the oral cavity. These oral hygiene preparations can be delivered to the oral cavity in several forms including: sprays, pre-rinses, rinses, pastes, gels and creams.

The coating substance defined in Hill '309 is not used to shield irritated or exposed inflamed tissue as suggested in the Office Action. Instead, the substance is delivered to the surface of the teeth, where it remains for a period of time – providing a protective barrier against plaque buildup.

Kim et al. teach the use of a specific extract of *Achyranthis radix* or *Ulmus cortex* as described therein as providing the desired effect of inhibiting the production of the periodontal disease-inducing agents and at the same time inhibiting the activity of the periodontal tissue-decomposing enzyme for periodontal tissues, as well as promoting collagen synthesis. As above, the term biofilm does not appear in the specification of the Kim patent.

As set forth above, the combined relevant teachings of the cited prior art patents neither teach nor suggest the specific regimen for the removal of biofilms in the treatment of pronounced gingival detachment as recited in the pending claims:

1. A self-treatment method of treating gingival detachment of at least 3 mm consisting of the steps of:
  - (a) physically removing biofilm from supragingival tooth surfaces by using a ribbed and grooved bristled toothbrush in combination with toothpaste containing soft abrasives;
  - (b) physically removing biofilm from interproximal tooth surfaces by using a

- ribbed and grooved bristled proxy brush in combination with proxy gel containing soft abrasives; and
- (c) physically removing biofilm from interproximal and subgingival tooth surfaces by using dental floss or dental tape containing releasable soft abrasives,

wherein the soft abrasives are physically worked into the supragingival, interproximal and subgingival biofilms, thereby assisting in the disruption and removal of said biofilms from tooth surfaces, thereby treating the gingival detachment.

At best, the cited prior art teaches merely selected elements of the claimed invention – but the “whole” invention claimed herein is neither taught nor suggested by the combined teachings of the cited art.

More importantly, the art further shows that there are many, many (likely thousands or more) methods available for the treatment of gingival detachment. How is the skilled artisan to pick and chose what could work from this vast array of available techniques?

This is not a *KSR* situation, where a limited number of treatments are available to the skilled artisan, and accordingly, the selection of the specific treatments defined in the claims is clearly not an obvious choice from the prior art. Instead, the claimed invention represents a patentable selection of specific treatments useful for the treatment of severe gingival detachment through specific means for the removal of biofilms.

Clearly the cited art does not make these techniques obvious, and the Section 103 rejection should be reconsidered and withdrawn. Such action is respectfully requested.

**TIME EXTENSION REQUEST**

Applicant respectfully requests a three month extension of time for the filing of this response. The original deadline was December 17, 2007. This response is being filed on or before March 17, 2008.

**FEE AUTHORIZATION**

Please charge all fees due in connection with this filing to Deposit Account No. 19-0733.

Respectfully submitted,

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